No. 80-2182

MOTION FILED

In The

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Supreme Court of the United States

October Term, 1980

INWOOD LABORATORIES, INC. and PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

and

BRIEF OF AMICUS CURIAE NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS, INC. IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

The National Association of Pharmaceutical Manufacturers, Inc., ("NAPM") by its undersigned General Counsel, respectfully moves, pursuant to Rules 36 and 42.2(b) of the Rules of this Court, for an order granting it leave to file an *amicus curiae* brief in support of the petition for a writ of certiorari filed in the above-entitled matter. The proposed brief is annexed hereto.

INTEREST OF THE AMICUS CURIAE

NAPM is a national trade association representing more than 100 manufacturers and distributors of prescription and "over-the-counter" pharmaceutical products throughout the United States. For many years, NAPM has been the leading spokesman for what is commonly known as the generic drug industry. NAPM has represented the industry in the courts (both as party and as an *amicus*), before administrative tribunals, as well as in the legislative arena by participating in hearings before Congress and the legislatures of numerous states. The petitioners herein, Inwood Laboratories, Inc. ("Inwood") and Premo Pharmaceutical Laboratories, Inc. ("Premo"), are members of NAPM.*

NAPM has reviewed the petition for a writ of certiorari filed by its members Inwood and Premo and concurs therein. However, upon such review, NAPM believes that certain additional important matters should be called to the Court's attention and for that purpose seeks to file its proposed *amicus curiae* brief.

The proposed brief succinctly discusses the following critical points in urging that this Court grant the petition for a writ of certiorari:

1. The historical nature of competition in the pharmaceutical field; and

2. The profound nationwide consequences which the decision of the United States Court of Appeals for the Second Circuit will cause unless review is granted.

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* The law firm of NAPM's General Counsel also represents Inwood, one of the petitioners herein.

As the representatives of the generic pharmaceutical industry, we respectfully believe that NAPM should be heard with regard to a petition for a writ of certiorari which vitally affects the interest of its members. Accordingly, pursuant to Rule 36.1 of this Court, the office of the undersigned communicated with counsel for the respondent to seek its consent to the filing of NAPM's *amicus* brief. Counsel for respondent declined to grant such consent and further declined to give any reasons for such refusal. Petitioners Inwood and Premo have consented to the filing of an *amicus* brief by their trade association.

It is respectfully requested that in deciding whether to grant certiorari in a matter vitally affecting the generic pharmaceutical industry, the Court should have the benefit of the additional views of that industry's trade association.

NAPM, by its General Counsel, a member of the Bar of this Court, therefore respectfully requests that NAPM's motion for leave to file the annexed *amicus* brief be granted.

Dated: New York, New York
July 23, 1981

Respectfully submitted,

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QUESTIONS PRESENTED

NAPM concurs in the questions presented in the petition for a writ of certiorari. For convenience, those questions are set forth below:

1. Whether the truthful, comparative use of another's trademark in labeling and advertising gives rise to liability for trademark infringement?

2. Whether Section 32 of the Lanham Act (15 U.S.C. §1114) grants a trademark owner monopoly rights in the color of its product?

TABLE OF CONTENTS

Page

Questions Presented i

Table of Contents iii

Table of Citations iii

Interest of the Amicus Curiae 1

Reasons for Granting the Writ:

The decision of the Second Circuit threatens the traditional pattern of competition in the pharmaceutical industry. 1

Conclusion 8

TABLE OF CITATIONS

Cases Cited:

F.T.C. v. Simeon Management Corp., 391 F. Supp. 697 (N.D. Cal. 1975), aff'd, 532 F. 2d 708 (9th Cir. 1976) 6

Hoffman La-Roche, Inc. v. Harris, 484 F. Supp. 58 (D.D.C. 1979) 8

Ives Laboratories, Inc. v. Darby Drug Co., Inc., 638 F. 2d 538 (2d Cir. 1981) 1, 2, 5, 6

Ives Laboratories, Inc. v. Darby Drug Co., Inc., 488 F. Supp. 394 (E.D.N.Y. 1980) 3, 7

Contents

Page

United States v. An Article . . . Acu-Dot, 483 F. Supp. 1311 (N.D. Ohio 1980) 6

Virginia State Board of Pharmacy v. Virginia Consumer Council, 425 U.S. 748 (1976) 3, 6, 7

Statute Cited:

Section 32 of the Lanham Act (15 U.S.C. §1114) ii

Other Authorities Cited:

"Competition in the Drug Industry: Hearings Before the Subcomm. on Oversight and Investigations of the House Committee on Energy and Commerce" (91 Cong., 1st Sess., March 10, 1981) 7, 8

Grussing, Purohit, Stewart, "Drug Product Selection in Illinois: An Evaluation of PA 80-976 After One Year of Experience" (May 30, 1980) 2

The American Druggist, "The Top 200 Prescription Drugs of 1980", Vol. 183 at 49 (Feb. 1981) 2

INTEREST OF THE AMICUS CURIAE

The interest of *amicus curiae* NAPM is set forth in its motion for leave to file the instant *amicus curiae* brief. *See* p. 2, *infra*. Accordingly, it will not be repeated herein.

REASONS FOR GRANTING THE WRIT

The decision of the Second Circuit threatens the traditional pattern of competition in the pharmaceutical industry.

NAPM wishes to emphasize to this Court that the labeling, advertising and color issues set forth by the petitioners do not stem from isolated marketing practices limited to the companies presently before the Court. Pharmaceutical products are known in the scientific community by their long and complicated chemical names. Historically, generic competition with large brand-name pharmaceuticals has been possible because the generic product could be identified only by designating it as a therapeutic equivalent for the more widely known brand-name pharmaceutical. Similarly, we respectfully advise the Court that the practice of marketing generic prescription products in the same color as that of brand-name products is firmly established, going back more than 50 years.

These twin aspects of the marketing of generic products, *i.e.*, identification of generic equivalents and marketing in similar color configurations, were an accepted part of the pharmaceutical trade and evoked no significant opposition from the brand-name drug companies until the last few years. Suddenly, these brand-name companies initiated a virtual avalanche of litigation against generic drug companies seeking to reverse the historical pattern, attacking both the use of similar colors and the manner of identification of generic equivalents. The decision of the United States Court of Appeals for the Second Circuit, in *Ives Laboratories, Inc. v. Darby Drug Co.*,

Inc., 638 F. 2d 538 (2d Cir. 1981) (hereinafter "*Ives*"), prohibits these long-standing competitive practices in the drug industry by invoking the novel theory of contributory trademark infringement.

The Court may wonder what accounts for this recent assault by brand-name companies upon these traditional modes of competition. The answer lies in the fact that it is only in recent years that generic drug competition has become a significant force in the marketplace.

During the past decade, forty-nine states, Puerto Rico and the District of Columbia, have adopted legislation which provides for substitution of less-expensive generic products for their brand-name counterparts when authorized by a physician. A detailed study of the effect of drug substitution laws recently conducted by the University of Illinois concluded that:

> "Data from the Illinois study *strongly supported the contention that significant cost savings accrued to consumers* when [drug substitution] occurred." *See* Grussing, Purohit, Stewart, "Drug Product Selection in Illinois: An Evaluation of PA 80-976 After One Year of Experience," Summary of Major Findings at 2 (May 30, 1980).

Moreover, the Illinois study of six other states[1] revealed that significant cost savings resulted in each state when generic drug substitution occurred. *Id.* at 87. The savings ranged from a low of $.86 to a high of $1.92 for *each* prescription. In 1980, more than 126 million prescriptions were filled in the United States. In December, 1980, the average retail price of a prescription was $9.20. *See The American Druggist*, "The Top 200 Prescription Drugs of 1980," Vol. 183 at 49, 52 (Feb. 1981). Thus, it can be

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1. Michigan, Wisconsin, Florida, Vermont, Rhode Island and Delaware.

readily agreed that the use of generic drugs affords the consumers of the nation potential savings of tens of millions of dollars.[2]

These substantial savings are jeopardized by the ill-founded decision of the Second Circuit in the *Ives* case. As Judge Nickerson noted in *Ives Laboratories, Inc. v. Darby Drug Co., Inc.*, 488 F. Supp. 394 (E.D.N.Y. 1980) (54a):

> "[T]he policy expressed in the New York Education Law [is] to encourage legal substitution of lower-priced drugs. . . . *To require different capsule colors . . . would also severely inhibit legal substitution which the legislature deems to be in the public interest." Id.* at 401 (69a).[3] (Emphasis added.)

The public interest in reducing the high cost of drugs was the impetus for the nearly unanimous adoption of drug substitution laws in the United States. Justice Blackmun eloquently articulated this interest in *Virginia State Board of Pharmacy v. Virginia Consumer Council*, 425 U.S. 748 (1976):

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2. For example, on April 10, 1981, the Department of Health for the State of New Jersey announced that its two-year old generic drug law saved consumers over $6 million. Similarly, on March 3, 1981, the New Hampshire Council on Aging stated that New Hampshire's then-proposed drug substitution law could save the elderly $2 million a year. One month prior, on February 3, 1981, a statewide community organization announced that if Texas adopted a drug substitution law, consumers would save upwards of $30 million. Texas became the 49th state to adopt such a law on May 28, 1981. Ten days later, on June 8, 1981, the New York City Department of Consumer Affairs announced that consumers had paid $12 million unnecessarily for medications because doctors and pharmacists have disregarded the state's generic drug law.

3. All "a" references are to the appendix annexed to the petition for certiorari.

> "Those whom the suppression of prescription drug price information hits the hardest are the poor, the sick, and particularly the aged. *A disproportionate amount of their income tends to be spent on prescription drugs;* yet they are the least able to learn, by shopping from pharmacist to pharmacist, where their scarce dollars are best spent. Where drug prices vary as strikingly as they do, information as to who is charging what becomes more than a convenience. It could mean the alleviation of physical pain or the enjoyment of basic necessities." *Id.* at 763-764. (Emphasis added.) *See also, id.* at 763, n.18.

What has happened is, therefore, obvious. Facing a growing public policy trend favoring lower-cost generic pharmaceutical products, the brand-name companies have reacted by seeking to undercut the traditional ability of the generic industry to compete effectively. The Second Circuit decision fosters this result by holding that identification of a drug product as a generic equivalent constitutes "trademark infringement", and engaging in a strained analysis to hold generic manufacturers liable as contributory trademark infringers. The result is a grant of monopoly color rights to brand-name companies and a *de facto* extension of their drug patents.

The far-reaching and potentially disastrous consequences of the Second Circuit decision derive from the fact that, in the first instance, it strikes at the very heart of the entire concept of generic competition.

The majority opinion failed to recognize that comparative advertising which cross-references a generic product to a brand-name product, is a long-established and essential custom of the trade. Such advertising is necessary since most purchasers,

including physicians, are only familiar with the brand-name product because of the enormous amount of money such companies spend in promotion to doctors and pharmacists. Indeed, physician unfamiliarity with generic names is evidenced by the structure of the New York generic substitution law, which permits the physician to list the brand-name product as the medication prescribed, but to sign his name on the prescription form above the heading "substitution permissible." In such an instance, a generic drug can be substituted for the brand-name product listed by the physician. Without cross-referencing generic products to brand-name products, widespread confusion would result.

If the trademark laws can be construed to prohibit the description of a drug product as a generic version of a brand-name product, the effective means of communication between the generic drug manufacturer, his customers, pharmacists and the ultimate consuming public, is virtually cut off. The unfamiliar technical chemical names offer no recourse. How many persons (even professional ones) know, for example, that such trademarked drugs as Darvon and Librium are identified respectively as Propoxyphene Hydrochloride and Chlordiazepoxide Hydrochloride?

To prohibit, as the Second Circuit does, identification of generic equivalents with brand-name products would cause chaos in the effort to market generic drugs.[4] As the dissenting opinion of Judge Mulligan points out, ". . . juxtaposition of the

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4. The Second Circuit holding of contributory trademark infringement was based on certain critical "additional evidence" adduced by respondent. *Ives*, 638 F. 2d at 542 (80a). Those instances all related to pharmacists who truthfully labeled or described the product as "Generic Cyclospasmol". No passing off or illegal substitution was involved. *Ives* holds that such labeling or description constitutes trademark infringement for which NAPM's members were held liable as "contributory infringers".

generic and brand-name drug would be imperative for generic manufacturers to compete effectively [citation omitted]." *Ives*, 638 F. 2d at 547, n. 4 (90a).

A more subtle, but no less significant consequence, flows from the monopoly rights granted to the brand-name companies in the color of their pharmaceutical products by virtue of the Second Circuit's decision. Obviously, these companies hope that a difference in color will induce consumers to resist generic drug products made available to them under the generic substitution laws. In view of Judge Nickerson's compelling factual findings as to the functionality of color, the Second Circuit's grant of a color monopoly (under the supposed rubric of contributory trademark infringement), virtually guarantees that the brand-name goal of consumer resistance to generic drugs will be realized.

The psychological reaction which all patients have to drugs which are designed to regulate critical body functions such as heart rate cannot be overstated, especially if the patient has been taking the same colored capsule or tablet for many years with positive therapeutic effects. Current medical theory recognizes that this type of psychological efficacy association produces an actual sympathetic therapeutic response to the condition being treated. *See e.g., United States v. An Article . . . Acu-Dot*, 483 F. Supp. 1311, 1314, n. 3 (N.D. Ohio 1980); *F.T.C. v. Simeon Management Corp.*, 391 F. Supp. 697, 705 (N.D. Cal. 1975), *aff'd*, 532 F. 2d 708 (9th Cir. 1976). It cannot be disputed that changes in color will interfere with the psychological efficacy association.

Moreover, generic substitution laws, which are designed to further the purposes which this Court protected in *Virginia Pharmacy*, will be severely undercut if the Second Circuit decision is left to stand. Simply put, the elderly, for whom the

particular drug at issue is primarily prescribed, will not purchase or will resist purchasing a generic drug which is different in color from the brand-name product which they have previously purchased for many years, even though the different colored generic would be less expensive. Indeed, the record shows dramatic evidence of a hospital's refusal to purchase the generic product at issue because it was not in the same color configuration as the brand-name counterpart marketed by respondent. *See Ives Laboratories, Inc. v. Darby Drug Co., Inc.*, 488 F. Supp. at 399 (64a).

NAPM's members and the generic drug industry seek nothing more than the opportunity to engage in vigorous *fair competition* with brand-name companies — competition which in recent years the brand-name companies have made every attempt to suppress.[5] *See, e.g.*, "Competition in the Drug Industry: Hearing Before the Subcommittee on Oversight and

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5. The petition for certiorari deals with the legal question of whether the actions of the pharmacist in truthfully labeling a product "Generic Cyclospasmol" constitute trademark infringement. NAPM respectfully wishes to add that the Second Circuit opinion, which seems to paint pharmacists as willing criminal cheaters of the public, stands in stark contrast to this Court's description of the "high degree of professionalism on the part of licensed pharmacists." *Virginia Pharmacy*, 425 U.S. at 766. The Court observed:

> "[That professionalism] is exercised in a number of ways for the *consumers benefit* . . . . *The expertise of the pharmacist* may supplement that of a prescribing physician. . . . The pharmacists, *a specialist in the potencies and dangers of drugs*, may even be consulted by the physician as to what to prescribe . . . .Some pharmacists . . .'monitor' the health problems and drug consumption of customers who come to them repeatedly. A pharmacist who has a continuous relationship with his customer *is in the best position, of course, to exert professional skills for the customer's protection.*" *Id.* at 766-767. (Emphasis added.)

Investigations of the House Committee on Energy and Commerce" (91 Cong., 1st Sess., March 10, 1981). *See also, Hoffman La-Roche, Inc. v. Harris*, 484 F. Supp. 58, 65 (D. D.C. 1979). The decision of the Second Circuit destroys that ability to effectively compete for the patient's dollar, and with the loss of that right comes the loss of savings in untold millions to consumers and a subversion of the generic substitution laws of this nation.

CONCLUSION

It is respectfully requested that for the reasons set forth herein a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Second Circuit.

Respectfully submitted,

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